

REMARKS

Claims 1-36 were pending in the present application. Claims 25 and 28 have been amended and claims 1-24 and 35-36 have been cancelled without prejudice to or disclaimer of the subject matter contained therein in view of the restriction requirement. Support for the amendment to claim 25 may be found at least in the Summary of the Invention and the Examples. Support for the amendment to claim 28 may be found at least in paragraph [0035] and is believed to clarify, not narrow, the claim language. Claims 25-34 remain pending.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

Election/Restrictions

Applicants acknowledge the treatment of the election as an election without traverse. The withdrawn claims have been canceled in view of the restriction requirement.

Information Disclosure Statement

Applicants note that the references which were lined through on the PTO-1449 were not considered. Applicants enclose herewith copies of the documents not considered for the Examiner's convenience. However, since the documents were submitted with an IDS in a parent application under 37 C.F.R. § 1.98(d) (see U.S. application no. 09/430,177; 57 documents submitted January 31, 2000), Applicants do not believe that a new information disclosure statement is required or that a fee is due under 37 C.F.R. § 1.97. Applicants note that each of the documents lined through on the present Form PTO-1449 was initialed by the examiner in the parent application (Office Action mailed April 6, 2001), indicating that the documents were available in the parent application. In view thereof, Applicants respectfully request that the enclosed documents be considered and the previously submitted Form PTO-1449 be initialed as to those documents currently lined through.

In the event the examiner believes the requirements of 37 C.F.R. § 1.97 have not been met, Applicants respectfully requests additional information. In addition, the Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-3218. This paper is submitted in duplicate.

Obviousness-Type Double Patenting Rejections

Claim 25 as amended is directed to an applicator for a polymerizable adhesive, comprising an applicator tip attached to an applicator body. The applicator tip is made by the method comprising mixing at least one active member selected from the group consisting of bioactive materials, flavorants, polymerization initiators and polymerization rate modifiers with precursor materials of a structural material of an applicator tip, and reacting the precursor materials to form the structural material of the applicator tip. The at least one active member is substantially uniformly dispersed within the structural material of the applicator tip.

As described in the specification, the active member is incorporated into the applicator tip during the manufacturing process of the structural material of the applicator tip. *Paragraph [0028]*. This provides active material in a substantially uniform distribution in the structural material. The more uniform distribution, as compared to methods applying the active material to the tip after manufacturing, provides a distinct structure with improved polymerization characteristics of the polymerizable material. *Paragraph [0036]*. The examples further demonstrate that improved polymerization set time results are obtained by the applicator tip as claimed compared to the initiator loading of prior methods. *Paragraph [0095]*.

Claims 1 and 25-34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25 and 76-102 of copending application no. 11/119,992. This rejection is moot in view of the Preliminary Amendment filed May 2, 2005, in the '992 application canceling claims 1-144. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 25-34 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-35 of U.S. Patent No. 6,637,967. Applicants respectfully traverse this rejection.

The cited claims of the '967 patent are directed to an article of manufacture for dispensing adhesive material. According to the Office Action, the present claims are not patentably distinct because while the copending claims do not recite instant process steps, the article of the copending claims read on a product with structure and composition commensurate with the instant product by process claims. Applicants disagree. As amended, the present claims are directed to a product which includes, by reacting the precursor materials containing the active material to form the structural material of the applicator tip,

active material in a substantially uniform distribution in the structural material. This is a structural distinction which would not have been obvious from the claims of the '967 patent since there is nothing to indicate the advantages of such a structure from the '967 patent claims. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 25-34 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,928,611. Applicants respectfully traverse this rejection.

The cited claims of the '611 patent are directed to an article of manufacture for dispensing a synthetic or semi-synthetic polymerizable or cross-linkable monomer material. According to the Office Action, the present claims are not patentably distinct because while the copending claims do not recite instant process steps, the articles of the copending claims read on products with structure and composition commensurate with the instant product by process claims. Applicants disagree. As amended, the present claims are directed to a product which includes, by reacting the precursor materials containing the active material to form the structural material of the applicator tip, active material in a substantially uniform distribution in the structural material. This is a structural distinction which would not have been obvious from the claims of the '611 patent since there is nothing to indicate the advantages of such a structure from the '611 patent claims. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 25-34 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,595,940. Applicants respectfully traverse this rejection.

The cited claims of the '940 patent are directed to a disposable applicator for dispensing and applying a material. According to the Office Action, the present claims are not patentably distinct because while the copending claims do not recite instant process steps, the article of the copending claims read on products with structure and composition commensurate with the instant product by process claims. Applicants disagree. As amended, the present claims are directed to a product which includes, by reacting the precursor materials containing the active material to form the structural material of the applicator tip, active material in a substantially uniform distribution in the structural material. This is a structural distinction which would not have been obvious from the claims of the '940 patent since there is nothing to indicate the advantages of such a structure from the '940 patent claims. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Claims 25-34 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,779,657. Applicants respectfully traverse this rejection.

The cited claims of the '657 patent are directed to a single-use applicator assembly for dispensing and applying a polymerizable monomeric adhesive material. According to the Office Action, the present claims are not patentably distinct because while the copending claims do not recite instant process steps, the articles of the copending claims read on products with structure and composition commensurate with the instant product by process claims. Applicants disagree. As amended, the present claims are directed to a product which includes, by reacting the precursor materials containing the active material to form the structural material of the applicator tip, active material in a substantially uniform distribution in the structural material. This is a structural distinction which would not have been obvious from the claims of the '657 patent since there is nothing to indicate the advantages of such a structure from the '657 patent claims. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 112

Claim 28 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "a polymerizable adhesive reservoir" was objected to by the Examiner. Claim 28 has been amended to clarify this language. In view thereof, Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 25-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/40797. Claims 25-34 were also rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,928,611 to Leung. Applicants respectfully traverse these rejections.

The '797 application and the '611 patent describe an impregnated applicator wherein a polymerization initiator or polymerization rate modifier is incorporated on an applicator tip. Incorporation of the initiator or the rate modifier into the applicator tip provides convenience because only a single composition is required, and allows a level of control over the polymerization rate that cannot be achieved through reliance on polymerization initiators or rate modifiers naturally present at the wound site. *Present specification, paragraph [0010]*.

The claimed applicator for a polymerizable adhesive comprises an applicator tip attached to an applicator body. The applicator tip is made by the method comprising mixing at least one active member selected from the group consisting of bioactive materials, flavorants, polymerization initiators and polymerization rate modifiers with precursor materials of a structural material of an applicator tip, and reacting the precursor materials to form the structural material of the applicator tip. The at least one active member is substantially uniformly dispersed within the structure material of the applicator tip. It has been discovered that applying or incorporating the active material when the applicator tip is initially formed has been found to provide an unexpectedly superior distribution profile of the material on, and within, the applicator tip. The superior distribution profile allows a reduction in polymerization time of the dispensed monomeric adhesive while avoiding tissue damage due to the highly exothermic polymerization reaction. *Paragraph [0018]*. A benefit of the applicator tip as claimed is that the active material applied to the applicator tip can be applied in a much more uniform manner as compared to the applicator tips previously described. That is, because the material is introduced during production of the applicator tip itself and is present during reaction of the precursor materials of the structural material for the applicator tip, the material becomes much more uniformly dispersed in the applicator tip material, rather than forming a gradient or only a surface coating on the applicator tip. This more uniform distribution in turn provides improved polymerization characteristics of the polymerizable material. *Paragraph [0036]; examples*.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since an applicator as claimed wherein the active material is mixed with precursor materials reacted to form the structural material such that the active material is substantially uniformly dispersed or incorporated into the structural material is not specifically disclosed in the '797 application or the '611 patent, the pending claims are not anticipated thereby. In view thereof, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, claims 25-34 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 9, 2007

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